



Billing Code 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-372]

Exempt Chemical Preparations Under the Controlled Substances Act

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Order with opportunity for comment.

SUMMARY: The applications for exempt chemical preparations received by the Drug Enforcement Administration (DEA) between April 1, 2016, and December 31, 2016, as listed below, were accepted for filing and have been approved or denied as indicated.

DATES: Interested persons may file written comments on this order in accordance with 21 CFR 1308.23(e). Electronic comments must be submitted, and written comments must be postmarked, on or before [INSERT DATE 60 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

ADDRESSES: To ensure proper handling of comments, please reference “Docket No. DEA-372” on all correspondence, including any attachments.

- *Electronic comments:* The Drug Enforcement Administration (DEA) encourages that all comments be submitted through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the Web page or to attach a file for lengthier comments. Please go to <http://www.regulations.gov> and follow

the online instructions at that site for submitting comments. Upon completion of your submission you will receive a Comment Tracking Number for your comment. Please be aware that submitted comments are not instantaneously available for public view on *Regulations.gov*. If you have received a comment tracking number, your comment has been successfully submitted and there is no need to resubmit the same comment.

- *Paper comments:* Paper comments that duplicate the electronic submission are not necessary and are discouraged. Should you wish to mail a comment *in lieu of* an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DRW, 8701 Morrisette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Michael J. Lewis, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: (202) 598-6812.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received are considered part of the public record and made available for public inspection online at <http://www.regulations.gov> and in the DEA's public docket. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase "PERSONAL IDENTIFYING

INFORMATION” in the first paragraph of your comment. You must also place all the personal identifying information you do not want posted online or made available in the public docket in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase “CONFIDENTIAL BUSINESS INFORMATION” in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment.

Comments containing personal identifying information and confidential business information identified as directed above will generally be made publicly available in redacted form. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be made publicly available. Comments posted to <http://www.regulations.gov> may include any personal identifying information (such as name, address, and phone number) included in the text of your electronic submission that is not identified as directed above as confidential.

An electronic copy of this document is available at <http://www.regulations.gov> for easy reference.

Legal Authority

The Drug Enforcement Administration (DEA) implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. Titles II and II are referred to as the “Controlled Substances Act” and the “Controlled

Substances Import and Export Act,” or the “CSA” for the purpose of this action. 21 U.S.C. 801–971. The DEA publishes the implementing regulations for these statutes in title 21 of the Code of Federal Regulations (CFR), chapter II.

The CSA and its implementing regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while ensuring an adequate supply is available for the legitimate medical, scientific, research, and industrial needs of the United States. Controlled substances have the potential for abuse and dependence and are controlled to protect the public health and safety.

Section 201 of the CSA (21 U.S.C. 811) authorizes the Attorney General, by regulation, to exempt from certain provisions of the CSA certain compounds, mixtures, or preparations containing a controlled substance, if he finds that such compounds, mixtures, or preparations meet the requirements detailed in 21 U.S.C. 811(g)(3)(B).¹ The DEA regulations at 21 CFR 1308.23 and 1308.24 further detail the criteria by which the DEA Assistant Administrator may exempt a chemical preparation or mixture from certain provisions of the CSA. The Assistant Administrator may, pursuant to 21 CFR 1308.23(f), modify or revoke the criteria by which exemptions are granted and modify the scope of exemptions at any time.

Exempt Chemical Preparation Applications Submitted Between April 1, 2016, and December 31, 2016

The Assistant Administrator received applications between April 1, 2016, and

¹This authority has been delegated from the Attorney General to the Administrator of the DEA by 28 CFR 0.100, and subsequently redelegated to the Deputy Assistant Administrator pursuant to Section 7 of 28 CFR 0.104, Appendix to Subpart R.

December 31, 2016, requesting exempt chemical preparation status detailed in 21 CFR 1308.23. Pursuant to the criteria stated in 21 U.S.C. 811(g)(3)(B) and in 21 CFR 1308.23, the Assistant Administrator has found that each of the compounds, mixtures, and preparations described in Chart I below is intended for laboratory, industrial, educational, or special research purposes and not for general administration to a human being or animal and either: (1) contains no narcotic controlled substance and is packaged in such a form or concentration that the packaged quantity does not present any significant potential for abuse; or (2) contains either a narcotic or non-narcotic controlled substance and one or more adulterating or denaturing agents in such a manner, combination, quantity, proportion, or concentration that the preparation or mixture does not present any potential for abuse; if the preparation or mixture contains a narcotic controlled substance, it must be formulated in such a manner that it incorporates methods of denaturing or other means so that the preparation or mixture is not liable to be abused or have ill effects if abused, and so that the narcotic substance cannot in practice be removed.

Accordingly, pursuant to 21 U.S.C. 811(g)(3)(B), 21 CFR 1308.23, and 21 CFR 1308.24, the Assistant Administrator has determined that each of the chemical preparations or mixtures generally described in Chart I below and specifically described in the application materials received by the DEA, is exempt, to the extent described in 21 CFR 1308.24, from application of sections 302, 303, 305, 306, 307, 308, 309, 1002, 1003, and 1004 (21 U.S.C. 822-823, 825-829, and 952-954) of the CSA, and 21 CFR 1301.74, as of the date that was provided in the approval letters to the individual

requesters.

Chart I

Supplier	Product Name	Form	Application Date
Aalto Scientific, Ltd.	Endocrine Program	Amber vial: 5 mL	8/23/2016
Aalto Scientific, Ltd.	Endocrinology	Amber vial: 5 mL	8/23/2016
Aalto Scientific, Ltd.	Linearity FD Testosterone, Siemens Centaur	Kit: 5 vials; 3 mL each	12/7/2016
Absolute Standards, Inc.	ISO G34 Calibrator Spike High	Glass ampoule: 1 mL	8/3/2016
Absolute Standards, Inc.	ISO G34 Calibrator Spike Low	Glass ampoule: 1 mL	8/3/2016
Absolute Standards, Inc.	ISO G34 Calibrator Spike Solution	Glass ampoule: 1 mL	8/3/2016
Absolute Standards, Inc.	ISO G34 Internal Standard	Glass ampoule: 1 mL	8/3/2016
Accriva Diagnostics, Inc.	Hemochron PT	Box: 45 cuvettes; 7.5µL each	5/17/2016
Arbor Assays	Testosterone 5-pack Enzyme Immunoassay Kit (K032-H5)	Kit: 400 µL vial	10/18/2016
Arbor Assays	Testosterone Enzyme Immunoassay Kit (ISWE001)	Kit: 1 mL vial	10/18/2016
Arbor Assays	Testosterone Enzyme Immunoassay Kit (K032-H1)	Kit: 90 µL vial	10/18/2016
Arbor Assays	Testosterone Standard (1,000 ng/mL)	Plastic vial: 1 mL	10/18/2016
Arbor Assays	Testosterone Standard (200,000 pg/mL)	Plastic vial: 90 µL	10/18/2016
Arbor Assays	Testosterone Standard (200,000 pg/mL)	Plastic vial: 400 µL	10/18/2016
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC252	Glass vial: 1 mL - 200 mL	7/29/2016
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC253	Glass vials: 1 ml - 200 mL	9/30/2016
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC254	Glass vial: 1 mL - 200 mL	7/29/2016
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC255	Glass vial: 1 mL - 200 mL	7/29/2016
Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC256	Glass vials: 1 ml - 200 mL	12/19/2016

Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC257	Glass vials: 1 ml - 200 mL	12/19/2016
Cayman Chemical Company	11-Keto Testosterone CRM; 1 mg/mL in Acetonitrile	Glass ampule: 1 mL	6/28/2016
Cayman Chemical Company	AB-CHMINACA (CRM); 1 mg/mL in Acetonitrile	Glass ampule: 1 mL	8/26/2016
Cayman Chemical Company	AB-CHMINACA (CRM); 1 mg/mL in Methanol	Glass ampule: 1 mL	8/26/2016
Cayman Chemical Company	AB-CHMINACA (CRM); 100 µg/mL in Acetonitrile	Glass ampule: 1 mL	8/26/2016
Cayman Chemical Company	AB-CHMINACA (CRM); 100 µg/mL in Methanol	Glass ampule: 1 mL	8/26/2016
Cayman Chemical Company	AB-PINACA CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	6/28/2016
Cayman Chemical Company	Acetyl Fentanyl CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	6/28/2016
Cayman Chemical Company	Acetyl Fentanyl CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	6/28/2016
Cayman Chemical Company	Cocaine CRM; 1 mg/mL in Acetonitrile	Glass ampule: 1 mL	6/28/2016
Cayman Chemical Company	Cocaine/Heroin/Methamphetamine Mixture CRM; 1 mg/mL each in Acetonitrile	Glass ampule: 1 mL	8/26/2016
Cayman Chemical Company	Cocaine/Heroin/Methamphetamine Mixture CRM; 100 µg/mL each in Acetonitrile	Glass ampule: 1 mL	8/26/2016
Cayman Chemical Company	Cocaine/Heroin/Methamphetamine Mixture CRM; 250 µg/mL each in Acetonitrile	Glass ampule: 1 mL	8/26/2016
Cayman Chemical Company	Cocaine/Heroin/Methamphetamine Mixture CRM; 500 µg/mL each in Acetonitrile	Glass ampule: 1 mL	8/26/2016
Cayman Chemical Company	GC-MS Drug Standard Mixture 1 in Acetonitrile	Glass ampule: 1 mL	6/28/2016
Cayman Chemical Company	Phytocannabinoid Mixture 1; 1 mg/mL in Acetonitrile	Glass ampule: 1 mL	6/28/2016
Cayman Chemical Company	Tapentadol (hydrochloride) CRM; 1 mg/mL in Acetonitrile	Glass ampule: 1 mL	8/26/2016
Cayman Chemical Company	Tapentadol (hydrochloride) CRM; 1 mg/mL in Methanol	Glass ampule: 1 mL	8/26/2016
Cayman Chemical Company	Tapentadol (hydrochloride) CRM; 100 µg/mL in Acetonitrile	Glass ampule: 1 mL	8/26/2016
Cayman Chemical Company	Tapentadol (hydrochloride) CRM; 100 µg/mL in Methanol	Glass ampule: 1 mL	8/26/2016
Cayman Chemical Company	THJ2201 (CRM); 1 mg/mL in Acetonitrile	Glass ampule: 1 mL	8/26/2016
Cayman Chemical Company	THJ2201 (CRM); 1 mg/mL in Methanol	Glass ampule: 1 mL	8/26/2016

Cayman Chemical Company	THJ2201 (CRM); 100 µg/mL in Acetonitrile	Glass ampule: 1 mL	8/26/2016
Cayman Chemical Company	THJ2201 (CRM); 100 µg/mL in Methanol	Glass ampule: 1 mL	8/26/2016
Cayman Chemical Company	ToxBox THC/THC Metabolite Plate	48-well plate	6/28/2016
Cerilliant Corporation	(±)-11-Hydroxy-delta9-THC glucuronide (0.01 mg/mL)	Glass ampule: 1 mL	11/11/2016
Cerilliant Corporation	(±)-Cannabicyclol (1.0 mg/mL)	Glass ampule: 1.0 mL	7/18/2016
Cerilliant Corporation	(±)-cis-3-Methylfentanyl HCl (0.05 mg/mL)	Glass ampule: 1 mL	6/21/2016
Cerilliant Corporation	(±)-cis-3-Methylfentanyl HCl (0.1 mg/mL)	Glass ampule: 0.5 mL	7/18/2016
Cerilliant Corporation	5alpha-Dihydrotestosterone-D3 [16, 16, 17-D3]; 10 µg/mL	Glass ampule: 1 mL	9/28/2016
Cerilliant Corporation	6beta-Naltrexol (1 mg/mL)	Glass ampule: 1 mL	5/6/2016
Cerilliant Corporation	AH-7921 HCl (1 mg/mL)	Glass ampule: 1 mL	5/20/2016
Cerilliant Corporation	AH-7921-D3 HCl (0.1 mg/mL)	Glass ampule: 1 mL	5/20/2016
Cerilliant Corporation	Brivaracetam-D3 (0.1 mg/mL)	Glass ampule: 1 mL	11/30/2016
Cerilliant Corporation	Butyryl fentanyl (0.05 mg/mL)	Glass ampule: 1 mL	6/21/2016
Cerilliant Corporation	Butyryl fentanyl (0.1 mg/mL)	Glass ampule: 0.5 mL	7/18/2016
Cerilliant Corporation	Cannabichromenic acid (CBCA) (1.0 mg/mL)	Glass ampule: 1 mL	11/30/2016
Cerilliant Corporation	Cannabicyclic acid (CBLA) (1.0 mg/mL)	Glass ampule: 1 mL	11/30/2016
Cerilliant Corporation	Carfentanil (0.1 mg/mL)	Glass ampule: 0.5 mL	9/28/2016
Cerilliant Corporation	Carfentanil oxalate (0.1 mg/mL)	Glass ampule: 0.5 mL	11/30/2016
Cerilliant Corporation	Carfentanil-D5 oxalate (0.1 mg/mL)	Glass ampule: 0.5 mL	11/30/2016
Cerilliant Corporation	Clorazepate dipotassium (1 mg/mL)	Glass ampule: 1 mL	5/6/2016
Cerilliant Corporation	Dihydrotestosterone Calibrator Level 1 (20 pg/mL)	Cryovial: 1 mL	8/12/2016
Cerilliant Corporation	Dihydrotestosterone Calibrator Level 2 (50 pg/mL)	Cryovial: 1 mL	8/12/2016
Cerilliant Corporation	Dihydrotestosterone Calibrator Level 3 (100 pg/mL)	Cryovial: 1 mL	8/12/2016

Cerilliant Corporation	Dihydrotestosterone Calibrator Level 4 (500 pg/mL)	Cryovial: 1 mL	8/12/2016
Cerilliant Corporation	Dihydrotestosterone Calibrator Level 5 (1000 pg/mL)	Cryovial: 1 mL	8/12/2016
Cerilliant Corporation	Dihydrotestosterone Calibrator Level 6 (2500 pg/mL)	Cryovial: 1 mL	8/12/2016
Cerilliant Corporation	Dihydrotestosterone Calibrator Level 7 (10 ng/mL)	Cryovial: 1 mL	8/12/2016
Cerilliant Corporation	Diphenoxylate HCl (1 mg/mL)	Glass ampule: 1 mL	5/20/2016
Cerilliant Corporation	Furanyl fentanyl (0.1 mg/mL)	Glass ampule: 0.5 mL	11/30/2016
Cerilliant Corporation	Norhydromorphone-D3 HCl (0.1 mg/mL)	Glass ampule: 1.0 mL	7/18/2016
Cerilliant Corporation	Noroxymorphone-D3 HCl (0.1 mg/mL)	Glass ampule: 1.0 mL	7/18/2016
Cerilliant Corporation	Pholcodine (1 mg/mL)	Glass ampule: 1 mL	5/6/2016
Cerilliant Corporation	Tapentadol-D3 HCl (1 mg/mL)	Glass ampule: 1 mL	11/11/2016
Cerilliant Corporation	U-47700 (1.0 mg/mL)	Glass ampule: 1 mL	11/30/2016
IDEXX Laboratories	Coag Dx PT	Box: 10 cartridges; 7.5µL each	10/21/2016
IDEXX Laboratories	Coag Dx PT Cartridge	Cartridges: 7.5µL each	10/21/2016
Immunalysis Corporation	cTHC Urine Calibrator 1 (20 ng/mL)	Dropper bottle: 5 mL, 15 mL	5/27/2016
Immunalysis Corporation	cTHC Urine Calibrator 2 (50 ng/mL)	Dropper bottle: 5 mL, 15 mL	5/27/2016
Immunalysis Corporation	cTHC Urine Calibrator 3 (100 ng/mL)	Dropper bottle: 5 mL, 15 mL	5/27/2016
Immunalysis Corporation	cTHC Urine Calibrator 4 (200 ng/mL)	Dropper bottle: 5 mL, 15 mL	5/27/2016
Immunalysis Corporation	cTHC Urine Control HIGH (62.5 ng/mL)	Dropper bottle: 5 mL, 15 mL	5/27/2016
Immunalysis Corporation	cTHC Urine Control LOW (37.5 ng/mL)	Dropper bottle: 5 mL, 15 mL	5/27/2016
Immunalysis Corporation	Fentanyl Urine Calibrator 1 (1 ng/mL)	Dropper bottle: 5 mL	5/27/2016
Immunalysis Corporation	Fentanyl Urine Calibrator 2 (2 ng/mL)	Dropper bottle: 5 mL	5/27/2016
Immunalysis Corporation	Fentanyl Urine Calibrator 3 (4 ng/mL)	Dropper bottle: 5 mL	5/27/2016
Immunalysis Corporation	Fentanyl Urine Control HIGH (1.5 ng/mL)	Dropper bottle: 5 mL	5/27/2016

Immunalysis Corporation	Fentanyl Urine Control LOW (0.5 ng/mL)	Dropper bottle: 5 mL	5/27/2016
Immunalysis Corporation	MDC Calibrator 1	Dropper bottle: 15 mL, 25 mL	5/27/2016
Immunalysis Corporation	MDC Calibrator 2	Dropper bottle: 15 mL, 25 mL	5/27/2016
Immunalysis Corporation	MDC Calibrator 3	Dropper bottle: 15 mL, 25 mL	5/27/2016
Immunalysis Corporation	MDC Calibrator 4	Dropper bottle: 15 mL, 25 mL	5/27/2016
Immunalysis Corporation	MDC Control HIGH Set 1	Dropper bottle: 15 mL, 25 mL	5/27/2016
Immunalysis Corporation	MDC Control HIGH Set 1	Dropper bottle: 15 mL, 25 mL	5/27/2016
Immunalysis Corporation	MDC Control LOW Set 1	Dropper bottle: 15 mL, 25 mL	5/27/2016
Immunalysis Corporation	MDC Control LOW Set 2	Dropper bottle: 15 mL, 25 mL	5/27/2016
Immunalysis Corporation	Opiates Urine Calibrator 2000 1 (1000 ng/mL)	Dropper bottle: 5 mL, 15 mL	5/27/2016
Immunalysis Corporation	Opiates Urine Calibrator 2000 2 (2000 ng/mL)	Dropper bottle: 5 mL, 15 mL	5/27/2016
Immunalysis Corporation	Opiates Urine Calibrator 2000 3 (4000 ng/mL)	Dropper bottle: 5 mL, 15 mL	5/27/2016
Immunalysis Corporation	Opiates Urine Calibrator 2000 4 (6000 ng/mL)	Dropper bottle: 5 mL, 15 mL	5/27/2016
Immunalysis Corporation	Oxazepam Urine Control HIGH (125 ng/mL)	Dropper bottle: 5 mL, 15 mL	5/27/2016
Immunalysis Corporation	Oxazepam Urine Control LOW (75 ng/mL)	Dropper bottle: 5 mL, 15 mL	5/27/2016
Instrumentation Laboratory	Gem Test PT	Box: 45 cuvettes; 7.5µL each	10/6/2016
IsoSciences, LLC	Codeine-[13C4, 15N], 1000 µg/mL in methanol	Amber ampule: 1 mL	10/20/2016
IsoSciences, LLC	Codeine-6β-Glucuronide-[13C10, 15N], 1000 µg/mL in methanol:water (2:8)	Amber ampule: 1 mL	10/20/2016
IsoSciences, LLC	Morphine-[13C4, 15N], 1000 µg/mL in methanol	Amber ampule: 1 mL	10/20/2016
IsoSciences, LLC	Morphine-6β-Glucuronide-[13C10, 15N], 1000 µg/mL in methanol:water (2:8)	Amber ampule: 1 mL	10/20/2016
IsoSciences, LLC	Testosterone-[2H8], 100 µg/mL in methanol	Amber Ampule: 1 mL	8/10/2016
IsoSciences, LLC	Testosterone-[2H8], 1000 µg/mL in methanol	Amber Ampule: 1 mL	8/10/2016

ITC	Hemochron Jr.	Box: 45 cuvettes; 7.5µL each	7/1/2016
Lipomed Inc.	25B-NB2OMe (1 mg/mL methanol)	Glass ampule: 1 mL	10/28/2016
Lipomed Inc.	25C-NB2OMe (1 mg/mL methanol)	Glass ampule: 1 mL	10/28/2016
Lipomed Inc.	25I-NB2OMe (1 mg/mL methanol)	Glass ampule: 1 mL	10/28/2016
Lipomed Inc.	25I-NB2OMe-D9 (0.1 mg/mL methanol)	Glass ampule: 1 mL	10/28/2016
Lipomed Inc.	25I-NB2OMe-D9 (1 mg/mL methanol)	Glass ampule: 1 mL	10/28/2016
Lipomed Inc.	3,4-Methylenedioxyprovalerone (1 mg/mL methanol)	Glass ampule: 1 mL	10/28/2016
Lipomed Inc.	3,4-Methylenedioxy- α - pyrrolidinopropiophenone (1 mg/mL methanol)	Glass ampule: 1 mL	10/28/2016
Lipomed Inc.	3-Desmethylprodine (1 mg/mL acetonitrile)	Glass ampule: 1 mL	10/28/2016
Lipomed Inc.	4-Ethylmethcathinone (1 mg/mL methanol)	Glass ampule: 1 mL	10/28/2016
Lipomed Inc.	4-Methylethcathinone (1 mg/mL methanol)	Glass ampule: 1 mL	10/28/2016
Lipomed Inc.	4-Methylmethcathinone (1 mg/mL methanol)	Glass ampule: 1 mL	10/28/2016
Lipomed Inc.	4-Methylmethcathinone-D3 (0.1 mg/mL methanol)	Glass ampule: 1 mL	10/28/2016
Lipomed Inc.	4-Methylmethcathinone-D3 (1 mg/mL methanol)	Glass ampule: 1 mL	10/28/2016
Lipomed Inc.	Benzodiazepines mixture (.001 mg free base/ml acetonitrile)	Glass ampule: 1 mL	10/28/2016
Lipomed Inc.	Benzodiazepines mixture 5 (1 mg free base/mL acetonitrile)	Glass ampule: 1 mL	10/28/2016
Lipomed Inc.	Bufotenine.oxalate.monohydrate (1 mg/mL methanol)	Glass ampule: 1 mL	10/28/2016
Lipomed Inc.	Butabarbital (1 mg/mL methanol)	Glass ampule: 1 mL	10/28/2016
Lipomed Inc.	Butalbital (1 mg/mL methanol)	Glass ampule: 1 mL	10/28/2016
Lipomed Inc.	Butalbital-D5 (1 mg/mL methanol)	Glass ampule: 1 mL	10/28/2016
Lipomed Inc.	Butylone (1 mg/mL methanol)	Glass ampule: 1 mL	10/28/2016
Lipomed Inc.	Cannabidiol-D3 (0.1 mg/mL methanol)	Glass ampule: 1 mL	10/28/2016
Lipomed Inc.	Cannabidiol-D3 (1 mg/mL methanol)	Glass ampule: 1 mL	10/28/2016

Lipomed Inc.	Cannabinol-D3 (0.1 mg/mL methanol)	Glass ampule: 1 mL	10/28/2016
Lipomed Inc.	Cannabinol-D3 (1 mg/mL methanol)	Glass ampule: 1 mL	10/28/2016
Lipomed Inc.	Carisoprodol (1 mg/mL methanol)	Glass ampule: 1 mL	10/28/2016
Lipomed Inc.	Clotiazepam (1 mg/mL methanol)	Glass ampule: 1 mL	10/28/2016
Lipomed Inc.	Cocaethylene-D3 (1 mg/mL acetonitrile)	Glass ampule: 1 mL	10/28/2016
Lipomed Inc.	Cocaine mixture 2 (1 mg/mL methanol)	Glass ampule: 1 mL	10/28/2016
Lipomed Inc.	Desomorphine (1 mg/mL acetonitrile)	Glass ampule: 1 mL	10/28/2016
Lipomed Inc.	Ethylone (1 mg/mL methanol)	Glass ampule: 1 mL	10/28/2016
Lipomed Inc.	JWH-018 (0.1 mg/mL methanol)	Glass ampule: 1 mL	10/28/2016
Lipomed Inc.	JWH-018 (1 mg/mL methanol)	Glass ampule: 1 mL	10/28/2016
Lipomed Inc.	JWH-018-D11 metabolite (0.1 mg/mL methanol)	Glass ampule: 1 mL	10/28/2016
Lipomed Inc.	JWH-018-D11 metabolite (1 mg/mL methanol)	Glass ampule: 1 mL	10/28/2016
Lipomed Inc.	JWH-019 (0.1 mg/mL methanol)	Glass ampule: 1 mL	10/28/2016
Lipomed Inc.	JWH-019 (1 mg/mL methanol)	Glass ampule: 1 mL	10/28/2016
Lipomed Inc.	JWH-081 (0.1 mg/mL methanol)	Glass ampule: 1 mL	10/28/2016
Lipomed Inc.	JWH-081 (1 mg/mL methanol)	Glass ampule: 1 mL	10/28/2016
Lipomed Inc.	JWH-122 (0.1 mg/mL methanol)	Glass ampule: 1 mL	10/28/2016
Lipomed Inc.	JWH-122 (1 mg/mL methanol)	Glass ampule: 1 mL	10/28/2016
Lipomed Inc.	JWH-200 (0.1 mg/mL methanol)	Glass ampule: 1 mL	10/28/2016
Lipomed Inc.	JWH-200 (1 mg/mL methanol)	Glass ampule: 1 mL	10/28/2016
Lipomed Inc.	L-Methamphetamine (1 mg/mL methanol)	Glass ampule: 1 mL	10/28/2016
Lipomed Inc.	Loprazolam (1 mg/mL methanol)	Glass ampule: 1 mL	10/28/2016
Lipomed Inc.	Mazindol (1 mg/mL Dimethylformamide)	Glass ampule: 1 mL	10/28/2016

Lipomed Inc.	Meprobamate (1 mg/mL methanol)	Glass ampule: 1 mL	10/28/2016
Lipomed Inc.	Methandienone (1 mg/mL methanol)	Glass ampule: 1 mL	10/28/2016
Lipomed Inc.	Methylone (1 mg/mL methanol)	Glass ampule: 1 mL	10/28/2016
Lipomed Inc.	Methylone-D3 (0.1 mg/mL methanol)	Glass ampule: 1 mL	10/28/2016
Lipomed Inc.	Methylone-D3 (1 mg/mL methanol)	Glass ampule: 1 mL	10/28/2016
Lipomed Inc.	N,N-Dimethylamphetamine (1 mg/mL methanol)	Glass ampule: 1 mL	10/28/2016
Lipomed Inc.	Naphyrone (1 mg/mL methanol)	Glass ampule: 1 mL	10/28/2016
Lipomed Inc.	Nimetazepam (1 mg/mL methanol)	Glass ampule: 1 mL	10/28/2016
Lipomed Inc.	Norbuprenorphine (1 mg/mL methanol)	Glass ampule: 1 mL	10/28/2016
Lipomed Inc.	Normeperidine (1 mg/mL methanol)	Glass ampule: 1 mL	10/28/2016
Lipomed Inc.	Pentedrone (1 mg/mL methanol)	Glass ampule: 1 mL	10/28/2016
Lipomed Inc.	Pentylone (1 mg/mL methanol)	Glass ampule: 1 mL	10/28/2016
Lipomed Inc.	Phenobarbital-D5 (side chain) (0.1 mg/mL methanol)	Glass ampule: 1 mL	10/28/2016
Lipomed Inc.	Phenobarbital-D5 (side chain) (1 mg/mL methanol)	Glass ampule: 1 mL	10/28/2016
Lipomed Inc.	Pregabalin (1 mg/mL methanol)	Glass ampule: 1 mL	10/28/2016
Lipomed Inc.	Propoxyphen-D5 (0.1 mg/mL methanol)	Glass ampule: 1 mL	10/28/2016
Lipomed Inc.	Propoxyphen-D5 (1 mg/mL methanol)	Glass ampule: 1 mL	10/28/2016
Lipomed Inc.	Pyrovalerone (1 mg/mL methanol)	Glass ampule: 1 mL	10/28/2016
Lipomed Inc.	α -Pyrrolidinopropiophenone (1 mg/mL methanol)	Glass ampule: 1 mL	10/28/2016
Lipomed Inc.	α -Pyrrolidinovalerophenone (1 mg/mL methanol)	Glass ampule: 1 mL	10/28/2016
Microgenics Corporation	Cascadion SM Total Testosterone Internal Standard	Box: 8 bottles, 29 mL each	12/16/2016
Microgenics Corporation	Cedia Buprenorphine OFT Control Set (Low and High) Catalog Number: 10022377	Vial: 10 mL; Box: 2 vials	11/15/2016
Microgenics Corporation	Cedia Buprenorphine OFT Cutoff Calibrator Catalog Number: 10022376	Vial: 5 mL; Box: 1 vial	11/15/2016

Microgenics Corporation	Cedia Multi-Drug OFT Cutoff Calibrator Set B Catalog Number: 10022355	Vial: 10 mL; Box: 1 vial	10/20/2016
Microgenics Corporation	Cedia Multi-Drug OFT Cutoff Control Set B (Low and High) Catalog Number: 10022356	Vial: 15 mL; Box: 2 vials	10/20/2016
Microgenics Corporation	Intercept i2he Multi-Drug Oral Fluid Cutoff Calibrator Set B Catalog Number: 1001-0419	Vial: 10 mL; Box: 1 vial	10/19/2016
Microgenics Corporation	Intercept i2he Multi-Drug Oral Fluid Cutoff Control Set B (Low and High) Catalog Number: 1001-0420	Vial: 15 mL; Box: 2 vials	10/19/2016
Microgenics Corporation	Thermo Scientific CEDIA Buprenorphine II Calibrator 10 ng/mL Catalog Number: 10020799	Vial: 5 mL Box: 1 vial	8/30/2016
Microgenics Corporation	Thermo Scientific CEDIA Buprenorphine II Calibrator 100 ng/mL Catalog Number: 10020802	Vial: 5 mL Box: 1 vial	8/30/2016
Microgenics Corporation	Thermo Scientific CEDIA Buprenorphine II Calibrator 20 ng/mL Catalog Number: 10020800	Vial: 5 mL Box: 1 vial	8/30/2016
Microgenics Corporation	Thermo Scientific CEDIA Buprenorphine II Calibrator 50 ng/mL Catalog Number: 10020801	Vial: 5 mL Box: 1 vial	8/30/2016
Microgenics Corporation	Thermo Scientific CEDIA Buprenorphine II Controls (Low and High) Catalog Number: 10020804	Vial: 5 mL Box: 4 vials	8/30/2016
Siemens Healthcare Diagnostics, Inc.	BK Emit II Plus Oxycodone Negative Control 100	Bulk Container: 1 L - 50 L	8/23/2016
Siemens Healthcare Diagnostics, Inc.	Emit II Plus Oxycodone Negative Control 100	Vial: 10 mL	8/23/2016
Siemens Healthcare Diagnostics, Inc.	Emit II Plus Oxycodone Negative Control 300	Vial: 10 mL	8/23/2016
Siemens Healthcare Diagnostics, Inc.	Emit II Plus Oxycodone Positive Control 100	Vial: 10 mL	8/23/2016
Siemens Healthcare Diagnostics, Inc.	Emit II Plus Oxycodone Positive Control 300	Vial: 10 mL	8/23/2016
Siemens Healthcare Diagnostics, Inc.	Emit II Plus Specialty Multi Drug Calibrator/Control Level 1	Vial: 10 mL	8/23/2016
Siemens Healthcare Diagnostics, Inc.	Emit II Plus Specialty Multi Drug Calibrator/Control Level 2	Vial: 10 mL	8/23/2016
Siemens Healthcare Diagnostics, Inc.	Emit II Plus Specialty Multi Drug Calibrator/Control Level 3	Vial: 10 mL	8/23/2016

Siemens Healthcare Diagnostics, Inc.	Emit II Plus Specialty Multi Drug Calibrator/Control Level 4	Vial: 10 mL	8/23/2016
Siemens Healthcare Diagnostics, Inc.	FC Emit II Plus Oxycodone Negative Control 100	Vial: 10 mL	8/23/2016
Siemens Healthcare Diagnostics, Inc.	FC Emit II Plus Oxycodone Negative Control 300	Vial: 10 mL	8/23/2016
Siemens Healthcare Diagnostics, Inc.	FC Emit II Plus Oxycodone Positive Control 100	Vial: 10 mL	8/23/2016
Siemens Healthcare Diagnostics, Inc.	FC Emit II Plus Oxycodone Positive Control 300	Vial: 10 mL	8/23/2016
Siemens Healthcare Diagnostics, Inc.	FC Emit II Plus Specialty Multi Drug Calibrator/Control Level 1	Vial: 10 mL	8/23/2016
Siemens Healthcare Diagnostics, Inc.	FC Emit II Plus Specialty Multi Drug Calibrator/Control Level 2	Vial: 10 mL	8/23/2016
Siemens Healthcare Diagnostics, Inc.	FC Emit II Plus Specialty Multi Drug Calibrator/Control Level 3	Vial: 10 mL	8/23/2016
Siemens Healthcare Diagnostics, Inc.	FC Emit II Plus Specialty Multi Drug Calibrator/Control Level 4	Vial: 10 mL	8/23/2016
Siemens Healthcare Diagnostics, Inc.	MP FC Emit Oxycodone Negative Control 100	Vial: 10 mL	8/23/2016
Siemens Healthcare Diagnostics, Inc.	MP FC Emit Oxycodone Negative Control 300	Vial: 10 mL	8/23/2016
Siemens Healthcare Diagnostics, Inc.	MP FC Emit Oxycodone Positive Control 100	Vial: 10 mL	8/23/2016
Siemens Healthcare Diagnostics, Inc.	MP FC Emit Oxycodone Positive Control 300	Vial: 10 mL	8/23/2016
Siemens Healthcare Diagnostics, Inc.	MP FC Emit Specialty Multi Drug Calibrator/Control LVL 1	Vial: 10 mL	8/23/2016
Siemens Healthcare Diagnostics, Inc.	MP FC Emit Specialty Multi Drug Calibrator/Control LVL 2	Vial: 10 mL	8/23/2016
Siemens Healthcare Diagnostics, Inc.	MP FC Emit Specialty Multi Drug Calibrator/Control LVL 3	Vial: 10 mL	8/23/2016
Siemens Healthcare Diagnostics, Inc.	MP FC Emit Specialty Multi Drug Calibrator/Control LVL 4	Vial: 10 mL	8/23/2016

Siemens Healthcare Diagnostics, Inc.	Pilot Emit II Plus Oxycodone Negative Control 100	Pilot container: 4 mL – 200 mL	8/23/2016
Siemens Healthcare Diagnostics, Inc.	Pilot Emit II Plus Oxycodone Negative Control 300	Pilot container: 4 mL – 200 mL	8/23/2016
Siemens Healthcare Diagnostics, Inc.	Pilot Emit II Plus Oxycodone Positive Control 100	Pilot container: 4 mL – 200 mL	8/23/2016
Siemens Healthcare Diagnostics, Inc.	Pilot Emit II Plus Oxycodone Positive Control 300	Pilot container: 4 mL – 200 mL	8/23/2016
Siemens Healthcare Diagnostics, Inc.	Pilot Emit II Plus Specialty Multi Drug Calibrator/Control LVL 1	Pilot container: 4 mL – 200 mL	8/23/2016
Siemens Healthcare Diagnostics, Inc.	Pilot Emit II Plus Specialty Multi Drug Calibrator/Control LVL 2	Pilot container: 4 mL – 200 mL	8/23/2016
Siemens Healthcare Diagnostics, Inc.	Pilot Emit II Plus Specialty Multi Drug Calibrator/Control LVL 3	Pilot container: 4 mL – 200 mL	8/23/2016
Siemens Healthcare Diagnostics, Inc.	Pilot Emit II Plus Specialty Multi Drug Calibrator/Control LVL 4	Pilot container: 4 mL – 200 mL	8/23/2016
USP	USP Levomethorphan Solution Reference Standard	Box: 3 vials, 1.2 mL each	9/13/2016
UTAK Laboratories, Inc.	AED II HR Serum Control, Ref: 72740	Carton: 5 bottles, 5 mL each	12/27/2016
UTAK Laboratories, Inc.	AED II MR Serum Control, Ref: 72741	Carton: 5 bottles, 5 mL each	12/27/2016
UTAK Laboratories, Inc.	Benzodiazepines 2 Serum Control HR, Ref: 22615	Carton: 5 bottles, 5 mL each	12/27/2016
UTAK Laboratories, Inc.	Benzodiazepines 2 Serum Control MR, Ref: 22616	Carton: 5 bottles, 5 mL each	12/27/2016
UTAK Laboratories, Inc.	Benzodiazepines Plus 100 Urine Control, Ref: 12090	Carton: 5 bottles, 5 mL each	12/27/2016
UTAK Laboratories, Inc.	Benzodiazepines Plus 100 Whole Blood Control, Ref: 12092	Carton: 5 bottles, 5 mL each	12/27/2016
UTAK Laboratories, Inc.	Benzodiazepines Plus 400 ng/mL Urine Control, Ref: 12091	Carton: 5 bottles, 5 mL each	12/27/2016
UTAK Laboratories, Inc.	Clonazepam Serum Control HR, Ref: 22610	Carton: 5 bottles, 5 mL each	12/27/2016

UTAK Laboratories, Inc.	Clonazepam Serum Control MR, Ref: 22611	Carton: 5 bottles, 5 mL each	12/27/2016
UTAK Laboratories, Inc.	DHEA Plus High Serum Control, Ref: 51411	Carton: 5 bottles, 3 mL each	12/27/2016
UTAK Laboratories, Inc.	DHEA Plus Low Serum Control, Ref: 51410	Carton: 5 bottles, 3 mL each	12/27/2016
UTAK Laboratories, Inc.	Pentobarbital Serum Control, Ref: 66319	Carton: 5 bottles, 5 mL each	12/27/2016
UTAK Laboratories, Inc.	Steroids Level 1 SMx Serum Control, Ref: 51401	Carton: 5 bottles, 3 mL each	12/27/2016
UTAK Laboratories, Inc.	Steroids Level 2 SMx Serum Control, Ref: 51402	Carton: 5 bottles, 3 mL each	12/27/2016
UTAK Laboratories, Inc.	Steroids Level 3 SMx Serum Control, Ref: 51403	Carton: 5 bottles, 3 mL each	12/27/2016
UTAK Laboratories, Inc.	Steroids Level 4 SMx Serum Control, Ref: 51404	Carton: 5 bottles, 3 mL each	12/27/2016

The Assistant Administrator has found that each of the compounds, mixtures, and preparations described in Chart II below is not consistent with the criteria stated in 21 U.S.C. 811(g)(3)(B) and in 21 CFR 1308.23. Accordingly, the Assistant Administrator has determined that the chemical preparations or mixtures generally described in Chart II below and specifically described in the application materials received by DEA, are not exempt from application of any part of the CSA or from application of any part of the CFR, with regard to the requested exemption pursuant to 21 CFR 1308.23, as of the date that was provided in the determination letters to the individual requesters.

Chart II

Supplier	Product Name	Form	Application Date
Aalto Scientific, Ltd.	General Chemistry Serum	Box: 1056 vials; 5 mL each	6/20/2016

Biochemical Diagnostics, Inc.	Detectabuse Custom Liquid Control Urine, MC253	Glass vial: 1 mL - 200 mL	7/29/2016
Cerilliant Corporation	(±)-cis-3-Methylfentanyl HCl (0.1 mg/mL)	Glass ampule: 1 mL	6/21/2016
Cerilliant Corporation	(±)-cis-3-Methylfentanyl HCl (1 mg/mL)	Glass ampule: 1 mL	5/6/2016
Cerilliant Corporation	Butyryl fentanyl (0.1 mg/mL)	Glass ampule: 1 mL	6/21/2016
Cerilliant Corporation	Butyryl fentanyl HCl (1 mg/mL)	Glass ampule: 1 mL	5/20/2016
Lipomed Inc.	Benzodiazepines mixture 8 (0.25 mg free base/mL acetonitrile)	Glass ampule: 1 mL	10/28/2016
Lipomed Inc.	Estazolam (1 mg/mL methanol)	Glass ampule: 1 mL	10/28/2016
Siemens Healthcare Diagnostics, Inc.	BK Emit II Plus Oxycodone Negative Control 300	Bulk Container: 1 L – 50 L	8/23/2016
Siemens Healthcare Diagnostics, Inc.	BK Emit II Plus Oxycodone Positive Control 100	Bulk Container: 1 L – 50 L	8/23/2016
Siemens Healthcare Diagnostics, Inc.	BK Emit II Plus Oxycodone Positive Control 300	Bulk Container: 1 L – 50 L	8/23/2016
Siemens Healthcare Diagnostics, Inc.	BK Emit II Plus Specialty Multi Drug Calibrator/Control LVL 1	Bulk Container: 1 L – 50 L	8/23/2016
Siemens Healthcare Diagnostics, Inc.	BK Emit II Plus Specialty Multi Drug Calibrator/Control LVL 2	Bulk Container: 1 L – 50 L	8/23/2016
Siemens Healthcare Diagnostics, Inc.	BK Emit II Plus Specialty Multi Drug Calibrator/Control LVL 3	Bulk Container: 1 L – 50 L	8/23/2016
Siemens Healthcare Diagnostics, Inc.	BK Emit II Plus Specialty Multi Drug Calibrator/Control LVL 4	Bulk Container: 1 L – 50 L	8/23/2016

Scope of Approval

The exemptions are applicable only to the precise preparation or mixture described in the application submitted to DEA in the form(s) listed in this order and only for those sections of the CSA and the CFR that are specifically identified. In accordance with 21 CFR 1308.24(h), any change in the quantitative or qualitative composition of the preparation or mixture, or change in the trade name or other designation of the

preparation or mixture after the date of application requires a new application. In accordance with 21 CFR 1308.24(g), the DEA may prescribe requirements other than those set forth in 1308.24(b)-(e) on a case-by-case basis for materials exempted in bulk quantities. Accordingly, in order to limit opportunity for diversion from the larger bulk quantities, the DEA has determined that each of the exempted bulk products listed in this order may only be used in-house by the manufacturer, and may not be distributed for any purpose, or transported to other facilities.

Additional exempt chemical preparation requests received between April 1, 2016, and December 31, 2016, and not otherwise referenced in this order may remain under consideration until the DEA receives additional information required, pursuant to 21 CFR 1308.23(d), as detailed in separate correspondence to individual requesters. The DEA's order on such requests will be communicated to the public in a future *Federal Register* publication.

The DEA also notes that these exemptions are limited to exemption from only those sections of the CSA and the CFR that are specifically identified in 21 CFR 1308.24(a). All other requirements of the CSA and the CFR apply, including registration as an importer as required by 21 U.S.C. 957.

Opportunity for Comment

Pursuant to 21 CFR 1308.23, any interested person may submit written comments on or objections to any chemical preparation in this order that has been approved or denied as exempt. If any comments or objections raise significant issues regarding any finding of fact or conclusion of law upon which this order is based, the Assistant Administrator

will immediately suspend the effectiveness of any applicable part of this order until he may reconsider the application in light of the comments and objections filed.

Approved Exempt Chemical Preparations are Posted on DEA's Web site

A list of all current exemptions, including those listed in this order, is available on the DEA's Web site at

http://www.DEAdiversion.usdoj.gov/schedules/exempt/exempt_chemlist.pdf. The dates of applications of all current exemptions are posted for easy reference.

Dated: May 24, 2017

Louis J. Milione,
Assistant Administrator.

[FR Doc. 2017-12110 Filed: 6/9/2017 8:45 am; Publication Date: 6/12/2017]